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Washington, D.C. 20231

FEB 18 1998

Gerald T. Bodner, Esq.
Hoffman & Baron
350 Jerico Turnpike
Jerico, NY 11753

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,724,231

NOTICE OF FINAL DETERMINATION

An application for extension of the patent term of U.S. Patent No. 4,724,231 under 35 U.S.C. § 156 was filed in the United States Patent and Trademark Office on January 3, 1997. The application was filed by Nastech Pharmaceutical Company, Inc., the patent owner of record. Extension is sought based upon the premarket review under § 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA) of a human drug product known by the tradename NASCOBAL™ having the active ingredient cyanocobalamin. NASCOBAL™ was approved for commercial use and sale by the Food and Drug Administration (FDA) on November 5, 1996.

A determination has been made that U.S. Patent No. 4,724,231 is **NOT** eligible for patent term extension under 35 U.S.C. § 156 based upon the regulatory review period of NASCOBAL™.

A single request for reconsideration of this FINAL DETERMINATION OF INELIGIBILITY may be made if filed by the applicant within TWO MONTHS of the mailing date of this letter. The period for response may be extended pursuant to 37 C.F.R. 1.136. See 37 C.F.R. 1.750. A failure to respond to this letter will result in the application papers being placed into the patent file with no further action taken on the application for patent term extension.

FDA's official records indicate that cyanocobalamin was previously approved for commercial marketing or use prior to the approval of NASCOBAL™. In a letter dated July 8, 1997, FDA stated:

> A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). However, our records also indicate that it **does not** represent the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in Glaxo Operations UK Ltd. v. Quigg, 706 F. Supp. 1224 (E.D. Va. 1989), aff'd, 894 F. 2d 392 (Fed. Cir. 1990). For example, BETALIN 12, CORBAVITE, CYANOCOBALAMIN, RUBRUMIN, RUVITE, and VIBISONE contain the same active ingredient as in NASCOBAL™, cyanocobalamin.

Under 35 U.S.C. § 156(a) a term of a patent which claims a product shall be extended if, *inter alia*, the product has been subject to a regulatory review period before its commercial

marketing or use. In addition, under § 156(a)(5)(A):

> the permission for the commercial marketing or use of the product . . . is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred; (Emphasis added)

Thus, the determination of eligibility of U.S. Patent No. 4,724,231 turns on the provisions in § 156(a)(5)(A) that the permission for the commercial marketing or use is the first permitted commercial marketing or use of the product. The term "product" is defined in 35 U.S.C. § 156(f) as follows:

> (f) For purposes of this section:
> (1) The term "product" means:
> (A) A drug product . . .
> (2) The term "drug product" means the active ingredient of -
> (A) A new drug, antibiotic drug, or human biological product . . . .including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient. (Emphasis added.)

By the explicit terms of section 156(f)(2), the term "product" as it relates to a human drug product means the active ingredient of the new drug product. The active ingredient in the approved product is cyanocobalamin. As noted in the above FDA letter and shown in the attachment thereto (pages 3-85 and 3-86 of the Prescription Drug Product List of the Approved Drug Products with Therapeutic Equivalence Evaluations, 17th Edition, 1997), the active ingredient cyanocobalamin had been approved for commercial marketing and use prior to the approval of the applicant's product. Furthermore, the prior approval of the active ingredient cyanocobalamin in BETALIN 12, CORBAVITE, CYANOCOBALAMIN, RUBRUMIN, RUVITE, and VIBISONE by the Food and Drug Administration was under section 505 of the FFDCA, the same provision of law under which regulatory review of the product NASCOBAL™ occurred. Applying the definition of "product" provided in section 156(f) to the extension requirement of § 156(a)(5)(A), applicant's product does not qualify as the first permitted marketing or use of the active ingredient. Since the approval of NASCOBAL™ was not the first permitted marketing or use of the active ingredient thereof, cyanocobalamin, the patent is not eligible for patent term extension based upon the regulatory review of NASCOBAL™. See In re Fisons Pharmaceuticals Limited, 231 USPQ 305 (Comm'r Pats. 1986); aff'd, Fisons plc v. Quigg, 8 USPQ2d 1491 (DDC 1988); aff'd, 10 USPQ2d 1869 (Fed. Cir. 1988); Glaxo Operations UK Ltd. v. Quigg, 13 USPQ 1628 (Fed. Cir. 1990).

In view of the above, the term of U.S. Patent No. 4,724,231 is not eligible for extension under 35 U.S.C. § 156 based upon the approval of the product NASCOBAL™ and the application for patent term extension, filed January 3, 1997, is dismissed.

Any correspondence with respect to this matter should be addressed as follows:

By mail:	Assistant Commissioner for Patents Box Patent Ext. Washington, D.C. 20231
By FAX:	(703) 308-6916 Attn: Special Program Law Office
By hand:	One Crystal Park, Suite 520 2011 Crystal Drive Arlington, VA

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin Tyson
Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

RE: NASCOBAL™
FDA Docket No.: 97E-0076

OIPE
APR 19 1999
PATENT & TRADEMARK OFFICE

DSP

PATENT
PTO/SB/123

CHANGE OF CORRESPONDENCE ADDRESS (Patent)		
Address to: Assistant Commissioner for Patents Washington, DC 20231	Patent Number	4,724,231
	Issue Date	02/09/1988
	Application Number	06/848,690
	Filing Date	04/08/1986
	First Named Inventor	Wenig
	Attorney Docket Number	719-16 CIP

Please change the Correspondence Address for the above-identified application to:

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☐ Customer Number:

OR

☒ Firm or Individual Name	Charles R. Hoffmann				
Address	Hoffmann & Baron, LLP				
Address	6900 Jericho Turnpike				
City	Syosset	State	New York	Zip Code	11791
County	Nassau				
Telephone	(516) 822-3550				

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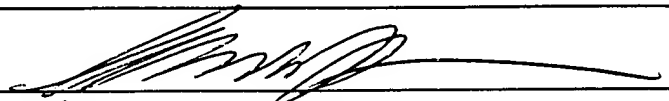
I am the:

☐ Applicant.

☐ Assignee of record of the entire interest. Certificate under 37 CFR 3.73(b) is enclosed.

☒ Attorney or agent of record.

Typed or Printed Name	Charles R. Hoffmann, Reg. No. 24,102
Signature	
Date	April 15, 1999

9200/1205

DSD

PTO/SB/21 (08-00)

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Approved for use through 10/31/2002. OMB 0651-0031

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APR 09 2001 PATENT & TRADEMARK OFFICE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Patent Number	4,724,231
Issued Date	February 9, 1988
First Named Inventor	Jeffrey Wenig
Group Art Unit	
Examiner Name	
Total Number of Pages in This Submission: 1	Attorney Docket Number: 20833000610

ENCLOSURES *(check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment / Response
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Assignment Papers *(for an Application)*
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition Routing Slip (PTO/SB/69) and Accompanying Petition
- ☐ Petition to Convert to a Provisional Application
- ☒ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s)
- ☐ After Allowance Communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) *(please identify below)*:
  Statement under 37 CFR 3.73(b)
  Return Receipt Postcard

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Remarks: The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430.

20350

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm and Individual name	Townsend and Townsend and Crew LLP Jeffrey J. King Reg No. 38,515
Signature	
Date	April 4, 2001

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on this date:

April 4, 2001

Typed or printed name	Linda Povinelli		
Signature		Date	April 4, 2001

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be send to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

SE 5007589 v1

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STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: Nastech Pharmaceutical Company, Inc.

Application No./Patent No.: 4,724,231 Filed/Issue Date: February 9, 1988

Entitled: Nasal Compositions Containing Vitamin B12

Nastech Pharmaceutical Company, Inc., a corporation

(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. ☒ the assignee of the entire right, title, and interest; or
2. ☐ an assignee of an undivided part interest

in the patent application/patent identified above by virtue of either:

A. ☒ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the Patent and Trademark Office at Reel 4567, Frame 0732, or for which a copy thereof is attached.

OR

B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as shown below:

1. From: _____ To :_____
   The document was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

2. From: _____ To :_____
   The document was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

3. From: _____ To :_____
   The document was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet.

☐ Copies of assignments or other documents in the chain of title are attached.

[**NOTE**: A separate copy (i.e., the original assignment document or a true copy of the original document) must be submitted to Assignment Division in accordance with 37 CFR Part 3, if the assignment is to be recorded in the records of the USPTO. See MPEP 302.8]

The undersigned (whose title is supplied below) is empowered to sign this statement on behalf of the assignee.

3/23/01
Date

Signature

Dr. Steven C. Quay
Typed or printed name

President and CEO
Title

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SE 5007473 v4

CIPE JC5
APR 0 9 2007
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REVOCATION OF POWER OF ATTORNEY OR AUTHORIZATION OF AGENT

Application Number	4,724,231 PATENT
Filing Date	February 9, 1988 ISSUED
First Named Inventor	Jeffrey Wenig
Group Art Unit	
Examiner Name	
Attorney Docket Number	20833000610

I hereby revoke all previous powers of attorney or authorizations of agent given in the above-identified application:

☐ A Power of Attorney or Authorization of Agent is submitted herewith.

OR

☒ Please change the correspondence address for the above-identified application to:

☒ Customer Number 20350 → *Place Customer Number Bar Code Label here*

OR

☐ Firm *or* Individual Name					
Address					
Address					
City					
Country		State		ZIP	
Telephone		Fax			

I am the:

☐ Applicant/Inventor.

☒ Assignee of record of the entire interest. See 37 CFR 3.71.
Certificate under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

SIGNATURE of Applicant or Assignee of Record

Name	Dr. Steven C. Quay
Signature	
Date	3/23/01

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

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SE 5007472 v4

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Case History For Docket Number: 719-16 CIP Country: USA

Report Run Date:02/11/1999

Application Number: 06/848,690
Application Date: 04/08/1986
Patent Number: 4,724,231
Grant Date: 02/09/1988
Client/Division: Nastech Pharmaceutical Company, Inc
Status: Granted
Attorney: GTB
KMM
KCH

EXAMINER:

G.A.U.:

Current Owner: Nastech Pharmaceutical Company, Inc
Inventors: Jeffrey Wenig
Title: Nasal Compositions Containing Vitamin B12

****

Action: Small Entity Status Completed Date: Due Date:

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
06/848,690	04/08/1986	JEFFREY WENIG	17864A

CONFIRMATION NO. 8265

OC000000006051136

20350
TOWNSEND AND TOWNSEND AND CREW
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

Date Mailed: 05/08/2001

NOTICE REGARDING POWER OF ATTORNEY

This is in response to the Power of Attorney filed 05/07/2001.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.